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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/700,417 | 11/29/2000 | Tony Kouzarides | 620-118 | 3566 |

7590 05/13/2003

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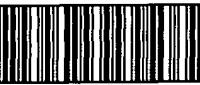
EXAMINER

CANELLA, KAREN A

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1642 | 17 |

DATE MAILED: 05/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|--|--------------------------------------|-----------------------------------|
| Office Action Summary | Application No. 09/700,417 | Applicant(s) Kouzarides |
| | Examiner Karen Canella | Art Unit 1642 |
|  | | |
| <i>-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --</i> | | |
| Period for Reply | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3 months</u> MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. | | |
| <p>- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.</p> <p>- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.</p> <p>- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.</p> <p>- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).</p> <p>- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).</p> | | |
| Status | | |
| 1) <input type="checkbox"/> Responsive to communication(s) filed on _____. | | |
| 2a) <input type="checkbox"/> This action is FINAL. 2b) <input checked="" type="checkbox"/> This action is non-final. | | |
| 3) <input type="checkbox"/> Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11; 453 O.G. 213. | | |
| Disposition of Claims | | |
| 4) <input checked="" type="checkbox"/> Claim(s) <u>1-10</u> is/are pending in the application. | | |
| 4a) Of the above, claim(s) _____ is/are withdrawn from consideration. | | |
| 5) <input type="checkbox"/> Claim(s) _____ is/are allowed. | | |
| 6) <input type="checkbox"/> Claim(s) _____ is/are rejected. | | |
| 7) <input checked="" type="checkbox"/> Claim(s) <u>1-10</u> is/are objected to. | | |
| 8) <input type="checkbox"/> Claims _____ are subject to restriction and/or election requirement. | | |
| Application Papers | | |
| 9) <input type="checkbox"/> The specification is objected to by the Examiner. | | |
| 10) <input type="checkbox"/> The drawing(s) filed on _____ is/are a) <input type="checkbox"/> accepted or b) <input type="checkbox"/> objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | |
| 11) <input type="checkbox"/> The proposed drawing correction filed on _____ is: a) <input type="checkbox"/> approved b) <input type="checkbox"/> disapproved by the Examiner. If approved, corrected drawings are required in reply to this Office action. | | |
| 12) <input type="checkbox"/> The oath or declaration is objected to by the Examiner. | | |
| Priority under 35 U.S.C. §§ 119 and 120 | | |
| 13) <input type="checkbox"/> Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) <input type="checkbox"/> All b) <input type="checkbox"/> Some* c) <input type="checkbox"/> None of: 1. <input type="checkbox"/> Certified copies of the priority documents have been received. 2. <input type="checkbox"/> Certified copies of the priority documents have been received in Application No. _____. 3. <input type="checkbox"/> Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). | | |
| *See the attached detailed Office action for a list of the certified copies not received. | | |
| 14) <input type="checkbox"/> Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e). a) <input type="checkbox"/> The translation of the foreign language provisional application has been received. | | |
| 15) <input type="checkbox"/> Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121. | | |
| Attachment(s) | | |
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | | |
| 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ | | |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | | |
| 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) | | |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ | | |
| 6) <input type="checkbox"/> Other: _____ | | |

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Response to Amendment

1. Claims 11-13 and 24-26 have been canceled. Claims 1-10 are pending and under consideration.
2. After review and reconsideration, the finality of the Office action of Paper No. 15 is withdrawn.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.
4. Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are vague and indefinite in the recitation of E2F and P/CAF as the only means of identifying the proteins upon which the claimed methods rely, because other laboratories can name the same proteins using different names. For instance, the specification states that P/CAF and GCN5 represent the same family of proteins, but it is not clear if P/CAF and GCN5 are synonyms or represent different proteins. Further, it is unclear if the recitation of P/CAF and E2F refers to two specific proteins, or if the recitation of P/CAF and E2F refers to two families of proteins. For purpose of examination all alternatives will be considered. Amendment of the claims to recite a sequence identifier or a deposit Accession Number would overcome this rejection.
5. Claims 1-10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 1-10 are method claims reliant upon the identity of E2F peptide and polypeptides and P/CAF polypeptides. The specification state on page 2, lines 3-11 that there

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are four families of proteins which can acetylate histones and names GCN5 and P/CAF as one "family". The specification does not further define P/CAF or set it forth as separate from GCN5. Thus the recitation of P/CAF encompasses a genus of proteins having the ability to acetylate histones, but whose structure is not defined by the specification. The specification states on page 4, lines 3-11 that full length E2F, truncated portions of E2F, or portions of E2F fused to other proteins or a suitable variant or derivative of any of these may be used and that the resulting acetylation may of any of the aforesaid may be assayed. The specification states on page 13, lines 6-12 that the present invention encompasses peptides which are sequence variants or derivatives of a wild type P/CAF or E2F sequence which retain the ability to interact with E2F or P/CAF respectively. The specification states on page 13, lines 22 to page 14 line 15 that the invention encompasses amino acid sequences which differ from the wild type P/CAF or E2F fragment by one or more amino acids by addition, insertion, deletion and substitution, and that variants, derivatives, alleles mutants and homologues from other organisms are included. The invention fails to define "wild type" P/CAF and E2F proteins in terms of amino acid sequences. Therefore, variants, derivatives, allelic mutants and homologues are also undefined. Thus the claims are dependent upon two separate genuses of proteins: P/CAF and E2F, and each of said genuses are highly variant because an unlimited amount of structural alterations are tolerated for the individual members of each genus. No common structural attributes identify the members of the genus. Since the disclosure fails to describe the common attributes or characteristic that identify members of the genus, and because the genus is highly variant, the recitation of E2F peptides, E2F polypeptide and P/CAF fail to describe the claimed genuses. One of skill in the art would reasonable conclude that the disclosure fails to provide a representative number of species to describe the claimed genuses. Thus, applicant was not in possession of the claimed genuses.

Claim 10 is drawn to a method according to any one of claims 1-5 and 9 further comprising formulating "a said agent" into a composition comprising at least one additional component. The method of claim 10 is reliant upon the genus of molecules encompassed by "at

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least one additional component". Neither the specification nor the claims limits said component in terms of the structural or functional attributes of said component. The genus of molecules encompassed by "component" is highly variant encompassing molecules having any function of any structure. One of skill in the art would reasonably conclude that the specification does not set forth a representative number of species to describe the claimed genus of "components". Thus applicant was not in possession of the claimed genus upon which the method of claim 10 relies.

6. All other rejections and objections as set forth in Paper No. 15 are withdrawn.
7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.


Karen A. Canella, Ph.D.

Patent Examiner, Group 1642

May 9, 2003